DEC 1 8 2001

K013570

510(k) Summary for the OSSEOTITE® Dental Implants

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.
Submitter	Implant Innovations, Inc. (*3i*)
Contact Person	Jacquelyn A. Hughes, RAC Director, Regulatory Affairs & Quality Assurance Implant Innovations, Inc. 4555 Riverside Drive Palm Beach Gardens, Florida 33410 Phone: 561-776-6819 Fax: 561-776-6852 E-mail: jhuges@3implant.com
Date Prepared	October 26, 2001
Name	OSSEOTITE® Dental Implants
Classification Names	Implants, Endosseous
Device Classification	Classification: Class III Classification Panels: Dental Regulation Number: 872.3640
Predicate Devices	• OSSEOTITE® Dental Implants, K983347 (cleared 1/99) • OSSEOTITE® Dental Implant System, K980549 (cleared 4/98) • *3i* Standard Threaded/Self-Tapping Threaded Implant, K935544 (cleared 3/95)

Performance Standards	Performance standards have not been established by the FDA under section 514 of the Federal, Food, Drug and Cosmetic Act
Device Description	The proposed OSSEOTITE® implants are identical to the predicate implants currently on the market, K983347, K980549, K935544.
Indications for Use	*3i* dental implants are indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment to restore a patient's chewing function.
Technological Characteristic	The proposed OSSEOTITE® implants are identical to the predicate implants currently on the market, K983347, K980549, K935544.
Summary of Testing Supporting the Change	*3i* has conducted a meta-analysis of clinical data on the OSSEOTITE® implants. The results indicate that there is no significant difference in the long-term cumulative survival of the OSSEOTITE® in smokers and non-smokers. A second analysis further demonstrates that the long-term survival of OSSEOTITE® implants in smokers is greater than that of *3i* machined implants in smokers. Thus, these data also further support not including smoking and tobacco use as a Warning or Precaution for the OSSEOTITE® implants.
Conclusion	The OSSEOTITE® implants with revised Instructions for Use labeling are substantially equivalent to the predicate OSSEOTITE® implants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2001

Ms. Jacquelyn A. Hughes
Director, Regulatory Affairs & Quality Assurance
Implant Innovations, Incorporated
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K013570
Trade/Device Name: Osseotite® Dental Implants
Regulation Number: 872.3640
Regulation Name: Implants, Endosseous
Regulatory Class: III
Product Code: DZE
Dated: November 27, 2001
Received: November 28, 2001

Dear Ms. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: OSSEOTITE® Dental Implants

Indications For Use:

3i dental implants are indicated for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment to restore a patient's chewing function.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K013570